PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 28 February 2001 (28.02.01)	
International application No. PCT/ES00/00026	**Applicant's or agent's file reference**
International filing date (day/month/year) 21 January 2000 (21.01.00)	**Priority date** (day/month/year) 25 January 1999 (25.01.99)
Applicant QUINTANILLA ALMAGRO, Eliseo et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

09 August 2000 (09.08.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer: Juan Cruz
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
2562WO227CEN		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/ES00/00026	21/01/2000	25/01/1999
International Patent Classification (IPC) or national classification and IPC A61K35/78		
Applicant ESPECIALIDADES FARMACEUTICAS CENTRUM, S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09/08/2000	07.02.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Fayos, C Telephone No. +49 89 2399 2180

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/ES00/00026

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-15 as originally filed

Claims, No.:

1-7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	-
Inventive step (IS)	Yes:	Claims	1-5
	No:	Claims	6-7
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	-

2. Citations and explanations
see separate sheet

Re Item IV

Lack of unity of invention

1- This Authority found that the requirement of unity of invention is not complied with for the following reasons:

1.1- Claims 1-5 refer to the use of Anapsos for the manufacture of a pharmaceutical medicament for regulation of the expression of adhesion molecules.

Claims 6-7 refer to the use of Anapsos for the manufacture of a pharmaceutical medicament for normalizing the lymphocyte CD4+CD29+CD45RA+ populations in pathologies where said populations are increased such as multiple sclerosis.

The use of a natural hydrosoluble extract of leaves of polypodium and/or the fraction soluble in alcohol and the liposoluble fraction of said extract (i. e. Anapsos) for the manufacture of a pharmaceutical medicament is taught by D1 and D2 (see item V 5- below).

1.2- The common concept linking claims 1-5 with claims 6-7 is hence not novel. Therefore, claims 1-5 and 6-7 are not so linked as to form a single general inventive concept (Rule 13.1 PCT) and give rise to the following inventions or groups of inventions:

Invention 1: use of Anapsos for the manufacture of a pharmaceutical medicament for regulation of the expression of adhesion molecules (claims 1-5)

Invention 2: use of Anapsos for the manufacture of a pharmaceutical medicament for normalizing the lymphocyte CD4+CD29+CD45RA+ populations in pathologies where said populations are increased such as multiple sclerosis (claims 6-7)

1.3- Despite the aforementioned objection, according to Rule 68.1 PCT. this Authority has chosen not to invite the applicant to restrict the claims or pay additional fees.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2- Reference is made to the following documents:

D1: ES 2 088 770
D2: EP 0503208

2.1- D1 and D2 were not cited in the search report. Both documents are known to the applicant and were cited in the description (respectively p 6 line 9 and p 5 line 25).

NOVELTY - Art. 33 (1) and (2) PCT

3- Claims 1-7 appear to be novel:

3.1- The novel features are the following:

- Use of Anapsos for the manufacture of a pharmaceutical medicament for regulation of te expression of adhesion molecules (invention 1) and,

- Use of Anapsos for the manufacture of a pharmaceutical medicament for normalizing the lymphocyte CD4+CD29+CD45RA+ populations in pathologies where said populations are increased such as multiple sclerosis (invention 2).

INVENTIVE STEP - Art. 33 (1), (2) and (3) PCT

4- Claims 1-5 (invention 1) appear to be inventive in the light of the available prior art.

4.1- The problem posed in the present application (invention 1) is to provide means for the regulation of the expression of adhesion molecules

The solution proposed is the use of Anapsos.

4.2- This use is neither disclosed, nor suggested by the available prior art, and hence, claims 1-5 can be considered as being inventive.

5- Claims 6-7 (invention 2) lack inventive step for the following reasons:

5.1- The problem posed in the present application (invention 2) is to provide means for normalizing the lymphocyte CD4+CD29+CD45RA+ populations in pathologies where said populations are increased such as multiple sclerosis.

The solution proposed is the use of the Anapsos.

5.2- D2 shows that a natural hydrosoluble extract obtained from leaves and/or rhizomes of Polypodium is active in the treatment of e. g. multiple sclerosis.

Hence, D2 represent the closest prior art.

5.3- D1 discloses the use of a natural hydrosoluble extract of leaves of polypodium and/or the fraction soluble in alcohol and the liposoluble fraction of said extract (i. e. Anapsos) for the manufacture of a pharmaceutical medicament for the treatment of cognitive and/or neuroimmune dysfunctions such as multiple sclerosis (D1 claim 1).

Furthermore, D1 shows (p 3 lines 10-11) that the immunological activity of said

extract resides, not only in the hydrosoluble fraction as shown in D2, but also in the fraction soluble in alcohol (i. e. liposoluble fraction) of said extract.

The extract of D1 is therefore also suitable for the treatment of multiple sclerosis (as mentioned in D2) and the use of Anapsos for the same use (treatment of multiple sclerosis) would then be obvious for the person skilled in the art.

Hence, claims 6-7 lack inventive step.

INDUSTRIAL APPLICABILITY - Art. 33 (1) and (4) PCT

6- Claims 1-7 appear to be industrially applicable.